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10/542,577

07/19/2005

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EXAMINER

KIM, TAEYOON

ART UNIT

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1651

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/542,577 | Applicant(s) UCHIDA ET AL. | |
| | Examiner TAEYOON KIM | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 17-21, 24-29, 32-34 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 17-21, 24-29, 32-34 and 36-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/2009 has been entered.

Applicant's amendment and response filed on 11/19/2009 has been received and entered into the case.

Claims 1-13, 15, 16, 22, 23, 30, 31, 35 and 40 are canceled, and claims 14, 17-21, 24-29, 32-34 and 36-39 are pending and have been considered on the merits. All arguments have been fully considered.

It is noted that the claim rejection based on Sugitachi has been modified from the previous OA.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 17-21, 24-29, 32-34 and 36-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention.

The limitation of “needle-punched fabric” in the current claims does not have proper support from the specification, and thus introduces a new matter to the application.

The particular limitation does not have a proper support in the original disclosure. The original disclosure requires a biodegradable synthetic nonwoven fabric, but does not disclose that the claimed invention particularly requires the non-woven fabric made by needle-punching. However, the instantly amended claims require the narrower limitation of a needle-punched biodegradable synthetic nonwoven fabric for the claimed method.

M.P.E.P. §2163 (I)(B) states “New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads). While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.”

Furthermore, M.P.E.P. §2163 (II)(B) states “If the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description, or in the case of a claim for priority under 35 U.S.C. 119, 120, or 365(c), the claim for priority must be denied.”

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In amended cases, subject matter not disclosed in the original application is sometimes added and a claim directed thereto. Such a claim is rejected on the ground that it recites elements without support in the original disclosure under 35 U.S.C. 112, first paragraph, *Waldemar Link, GmbH & Co. v. Osteonics Corp.* 32 F.3d 556, 559, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994); *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). See MPEP § 2163.06 - § 2163.07(b) for a discussion of the relationship of new matter to 35 U.S.C. 112, first paragraph. New matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method. See MPEP § 608.04 to § 608.04(c). See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) and MPEP § 2163.05 for guidance in determining whether the addition of specific percentages or compounds after a broader original disclosure constitutes new matter.

While applicant argued in the current amendment as well as in the reply mailed on 11/27/2007 that the non-woven fabric disclosed in Example 1 of the specification (i.e. Neoveil) may be made by "needle-punching" as described in Japanese patent 18579/1993 (English translation provided by applicant), the English translation of the Japanese Patent cannot be considered as "inherent" support for the nonwoven fabric of the specification (i.e. Neoveil) is made by needle punching. The abstract discloses that nonwoven fabric or woven or knitted fabric made from the multifilament of the polymer, and pledget is made of the fabrics by needle punching. Thus, the nonwoven fabric disclosed by the Japanese patent (PGA fabric; Neoveil) is not necessarily considered as "needle punched", rather the pledget taught by the Japanese Patent is made of Neoveil by piling the fabrics and needle punching followed by pressing under heating.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 17-21, 24-29, 32-34 and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugitachi et al. (of record) in view of Greenawalt et al. (of record) in further view of Koyfman et al. (US 5,393,594).

Sugitachi et al. teach an absorbable material such as polyglycolic acid (PGA) comprising thrombin, and a process of making such is by dipping the material in saline solution of thrombin and then lyophilized (see Examples 2 and 6).

Sugitachi et al. also teach the absorbable material being non-woven fabric (col. 1, lines 49-55).

Although Sugitachi et al. do not teach the material comprising fibrinogen, it would have been obvious to a person of ordinary skill in the art to use fibrinogen separately or together with thrombin/PGA fibers of Sugitachi et al., because it is notoriously well known in the art that the role of thrombin is to activate fibrinogen to fibrin to form a fibrin network, and fibrinogen is commonly added to thrombin or visa versa. For example, a fibrin sealant, TisseelTM, disclosed by Greenawalt et al. comprises two-component system: fibrinogen component and thrombin component, and fibrinogen component comprising Factor XIII, to be mixed before the use the system (see column 1, lines 20-30). Thus, a person of ordinary skill in the art would recognize that additional fibrinogen comprising Factor XIII taught by Greenawalt et al. applied to the

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thrombin/PGA fabric of Sugitachi et al. before the use of thrombin/PGA fabric to a wound site would enhance and/or facilitate the formation of fibrin network, instead of utilizing fibrinogen present in the plasma of a patient being treated with a reasonable expectation of success.

Furthermore, since the use of fibrinogen along with thrombin is well known in the art as a hemostatic composition, it would have been obvious to a person of ordinary skill in the art to try fibrinogen applied to the thrombin/PGA fabric of Sugitachi et al. prior to the use of the fabric to a wound site to stop bleeding with reasonable expectation of success in using the thrombin/PGA fabric along with fibrinogen/Factor XIII of Greenawalt et al.

With regard to the elastic property of the hemostatic material of the current invention, the non-woven fabric made of PGA comprising thrombin taught by Sugitachi et al. would have inherently possessed the same property as the claimed invention because the material of the references is considered the same or substantially identical to the claimed invention.

M.P.E.P. § 2112 recites, “Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established.” *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

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With regard to the hemostatic kit of the current invention, Greenawalt et al. teach a hemostatic kit comprising multiple hemostatic compositions in a separate package. It is well known in the art hemostatic compositions are packaged in a form of kit as shown by TisseelTM (see column 1, lines 20-22) and the teaching of Greenawlat et al. (see column 6, lines 51-59).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to try to prepare the hemostatic materials of Sugitachi et al. (i.e. thrombin/PGA) along with fibrinogen/Factor XIII of TisseelTM disclosed by Greenawalt et al. in a format of a kit. See *KSR v. Teleflex* (550 US82 USPQ2d 1385, 2007).

With regard to the limitation drawn to the non-woven fabric being made by needle-punching, since needle punching is one of well known techniques/methods in the art for making nonwoven fabrics according to Koyfman et al. (see col. 1, lines 24-34), it would have been obvious to a person of ordinary skill in the art to use a non-woven fabrics made by a needle-punching technique for the nonwoven fabric of PGA used in Sugitachi et al. in view of Greenawalt et al.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 14 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5 and 6 of copending Application No. 11/941,779.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications disclose a method of preparing nonwoven fabric comprising PGA holding thrombin by immersing the fabric into a saline or buffer solution containing thrombin, followed by lyophilizing the fabric. Although the claims of '779 application do not particularly teach a step of adding fibrinogen immediately prior to use of the thrombin-PGA fabric, it would have been obvious to a person of ordinary skill in the art to use fibrinogen because it is notoriously well known in the art that the role of thrombin is to activate fibrinogen to fibrin to form a fibrin network, and fibrinogen is commonly added to thrombin as a hemostatic purpose. Therefore, the claims of '779 application render the claim of instant application obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-9041.

The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651